4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0677]

Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dental Products Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 18th, 2013, from 8 a.m. to 2:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD, 20877. The hotel phone number is 301-977-8900.

Contact Person: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 1611, Silver Spring, MD, Sara.Anderson@fda.hhs.gov, 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and

scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 18, 2013, the committee will discuss and make recommendations on the proposed regulatory classification for dental devices known as Endosseous Dental Implants (Blade-form), one of the remaining preamendments Class III devices. The Class III blade-form endosseous dental implant is a device placed into the maxilla or mandible and composed of biocompatible material, such as commercially pure titanium, with sufficient strength to support a dental restoration, such as a crown, bridge, or denture, intended for the purpose of replacing tooth (or teeth) roots and extending a support post through the gingival tissue into the oral cavity to restore chewing function. The blade-form implant is generally a rectangular shape or rounded corner rectangle shape (in the mesio-distal plane) with a narrow tapered (narrow at the apical edge) edge (in the bucco-lingual plane) similar in shape to a razor blade. Other blade designs, such as square, V-shaped, and triangles have also been used. The blade-form implants are either one-piece or two-piece implants designed with one to three cylindrical abutment posts extending from the coronal aspect of the blade through the soft tissue and into the oral cavity.

On January 4, 2013 (FDA-2012-N-0677), FDA issued a proposed order which, if made final, would reclassify the blade-form endosseous dental implant into class II (special controls). The committee's discussion will involve making recommendations regarding regulatory classification to either reaffirm Class III or reclassify these devices into Class II and comment on whether the proposed Special Controls are adequate to reasonably ensure the safety and effectiveness of blade-form endosseous dental implants. The regulatory history of blade-form endosseous dental implant has been discussed as part of the proposed order (FDA-2012-N-0677).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 9, 2013. On July 18, 2013, oral presentations will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 28, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 1, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you

require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at Annmarie.Williams@fda.hhs.gov or 301 796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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